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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,954	01/09/2004	Kathleen M. Smith	ST8777US	8832
22203	7590	07/20/2006	EXAMINER	
KUSNER & JAFFE HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143			GARG, YOGESH C	
			ART UNIT	PAPER NUMBER
			3625	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/754,954

Applicant(s)

SMITH ET AL.

Examiner

Yogesh C. Garg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5 and 14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 14 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Response to Amendment***

1. Applicant's amendment received on May 15, 2006 is acknowledged and entered. The applicant has amended claim 1, canceled claims 6-10 & 12 and added a new claim 14. Currently claims 1- 5, and 14 are pending for examination.

***Response to Arguments***

2. Applicant's arguments with respect to currently amended claim 1 have been considered but are moot in view of the new ground(s) of rejection necessitated due to amendments.

***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because:

Claim 14, an apparatus/system claim, recites within its scope a human being, that is an operator being part of the claimed system and is used to enter the operator identifier while starting and ending an antimicrobial cycle. A system/apparatus claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. The applicant's attention is kindly referred to recent ruling by the US Patent and Trade Mark Office, Board of Appeals and Interferences (Ex Parte Bowman, 61 USPQ2d 1669) (Unpublished)) .

Also please refer to a decision by the Board of Patent Appeals and Interferences In Ex parte Allen, ;,- USPQ (Bd. App. & Int. April 3, 1987), " on "Animal – Patentability-", held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court In Diamond v. Chakrabarty. 447 U.S. 303, 206 USPQ 193 (1980) as it had done In EX parte Hibberd. 227 USPQ 443 (Bd. App. & Int., 1985), as controlling authority that Congress Intended statutory subject matter to "Include anything under the sun that is made by man. The Patent and Trademark office now considers nonnaturally occurring non-human multicellular living organisms, Including animals, to be patentable subject matter within the scope of 35 U.S.C. 101. The Board's decision does not affect the principle and practice that products found In nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature In accordance with existing law. -See e.g. Funk Bros, Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 76 USPQ 280 (1948); American Fruit Growers v. Brogdex. 283 U.S. 1, 8 USPQ 131 (1931); Ex parte Grayson. 51 USPQ 413 (Bd. App. 1941).

**A claim directed to or including within its scope a human being will not be considered to be Patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, It Is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope Include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. In re Wakefield, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).**

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The amended claim(s) contains subject matter, that is , “instrument tracking client assigns (3) an operator identifier for identifying an operator of the antimicrobial device identified by the device identifier” (see amended claim 1), which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant, in his remarks, has not indicated support in the specification for the above amendment. On reviewing the applicant's specification, the examiner observes that the operator's code is existing and is not assigned by a tracking client. The operator enters his code when removing a load from an antimicrobial device and this code is not received by him from the tracking client. Further in Table 1 of the applicant's disclosure a “SetMessage Function” includes sending a message about adding operator to device with his name and code but does not teach assigning an identifier to an operator. In fact, the operator's name and code already exist and they are used to add an operator to a device. From the applicant's specification, as best understood by the examiner, the tracking client sends a message to add an operator to operate the device and that message includes the operator's name and code. But it does not assign an identifier to an operator.

***Objection to Specification***

5. The amendment filed 5/15/2006 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "instrument tracking client assigns (3) an operator identifier for identifying an operator of the antimicrobial device identified by the device identifier" (see amended claim 1). The applicant, in his remarks, has not indicated support in the specification for this added subject matter. On reviewing the applicant's specification, the examiner observes that the operator's code is existing and is not assigned by a tracking client. The operator enters his code when removing a load from an antimicrobial device and this code is not received by him from the tracking client. Further in Table 1 of the applicant's disclosure a "SetMessage Function" includes sending a message about adding operator to device with his name and code but does not teach assigning an identifier to an operator. In fact, the operator's name and code already exist and they are used to add an operator to a device. From the applicant's specification, as best understood by the examiner, the tracking client sends a message to add an operator to operate the device and that message includes the operator's name and code. But it does not assign an identifier to an operator.

Applicant is required to cancel the new matter in the reply to this Office Action.

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6.1. Claims 1-2, 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman et al. (US Publication 2005/0137653), hereinafter, referred to Friedman in view of

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Sanaka et al. (US Patent 5,696,896), hereinafter referred to Sanaka and further in view of Amhof et al. (US Patent 6,238,623), hereinafter referred to Amhof..

Note: Claims 1-2, 4-5 14 are apparatus/system claims. Claims Directed to an Apparatus must be distinguished from the prior art in terms of structure rather than function, *In re Danly* 263 F.2d 844, 847, 120 USPQ 582, 531 (CCPA 1959). A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1657 (bd Pat. App. & Inter. 1987). The combined prior arts of Friedman/Sanaka discloses the structural limitations of claims 1-2, 4-5, that is analogous information management system comprising a communication server interface, a tracking client computer and an antimicrobial device such that it is capable of performing the recited limitations that is the server interface is capable of receiving data from clients and transmit that data to the device. Therefore, the functional limitations of the claims do not distinguish the claimed apparatus from the prior art.

Regarding claim 1, Friedman discloses an information management system (Friedman discloses an information management system which is analogous to the one claimed by the applicant. See Fig.1 and paragraphs 0013, 0042-0043. Friedman discloses a communication server interface "30" in bi-directional communication with the at least one instrument tracking client [reference numbers "34", "36", "38", ... "42" ... "46" represent tracking clients] and the at least one antimicrobial treatment device [reference number "12" ]. Said communication server interface "30" is programmed to: receive data from the instrument tracking clients and transmit data to an antimicrobial device) for tracking instruments and is capable of comprising:

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at least one instrument tracking client, each instrument tracking client installed on a respective general purpose computer (see at least paragraph 0041 and the reference numbers "34", "36", "38", ... "42"... "46" I Fig.1. The computer systems represented by numbers "34", "36", "38", ... "42"... "46" are associated with different departments and correspond device/instrument tracking clients installed on computer systems to communicate with other server/computer via communication network and are capable of implementing the functions as claimed by the applicant. );

at least one antimicrobial treatment device (See Fig.1, reference number "12" [also at least paragraphs 0042-0043] which is a computerized medical device capable of bi-directional communication with the information system server "30"). Note: Both the claim limitation and the applicant's specification do not elaborate on the functional details of this device except that the communication server can send commands to it and receives data from it. Sending commands and receiving data is also performed by "12" medical device disclosed in Friedman. Friedman does not disclose that the device is an antimicrobial treatment device for reducing microbial contamination of a medical instrument by means of at least one treatment agent. However, in the same field of endeavor, Sanaka discloses an information management system for tracking a sterilizer, that is antimicrobial treatment device which is capable for reducing microbial contamination of a medical instrument by means of at least one treatment agent (see at least " 15 Sterilizer " in Fig.1 which corresponds to antimicrobial device, also see col.4, lines 50-57). In view of Sanaka, it would have been obvious to one of an ordinary skilled in the art at the time of the applicant's invention to have modified Friedman to include stabilizer along with other medical devices, such as pumps, physiological monitors, etc. because it will enhance Friedman's information management system to include monitoring the functioning of sterilizers/washers which, as



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known to one of an ordinary skilled in the art are used in hospitals to wash and sterilize the medical instruments .

Friedman does not teach the intended function/use of the said instrument tracking clients that is to assign a device identifier for identifying an antimicrobial treatment device; a load identifier for identifying one or more medical instruments treated together using the antimicrobial treatment device identified by the device identifier, and an operator identifier for identifying an operator of the antimicrobial device identified by the device identifier. As analyzed above, Friedman's clients, "34", "36", "38", ... "42" ... "46" in Fig.1 are capable of implementing this function. In the same field of endeavor, Sanaka discloses assigning a device identifier for identifying each of the antimicrobial treatment devices and a load identifier for identifying medical instruments treated together using a first antimicrobial treatment process (see at least Figs.9, 31 and col.12, lines 30-55). In view of Sanaka, it would have been obvious to one of an ordinary skilled in the art at the time of the applicant's invention to have modified Friedman/Sanaka as already applied to claim 1 above to include the feature that the clients monitoring the functioning of sterilizers/washers assigns a device identifier for identifying each of the antimicrobial treatment devices and a load identifier for identifying medical instruments treated together using a first antimicrobial treatment process because it will enable the clients to correlate the items being sterilized, such as lenses in Sanaka, to be identified as when and in which sterilizer run they were sterilized and to generate and store such records for future references.

Friedman combined with Sanaka also does not disclose the intended use/function of the client to assign an operator identifier for identifying an operator of the antimicrobial device identified by the device identifier. As analyzed above, Friedman's clients, "34", "36", "38", ... "42" ... "46" in Fig.1 are capable of implementing this function. In the same field of endeavor,

that is sterilizing products, Amhof teaches assigning an operator identifier for identifying an operator of the antimicrobial device identified by the device identifier (see at least col.5, lines 11-25, " *The printed indicia on the first portion may optionally comprise sterilization equipment identification, sterilization conditions, dates, general comments, validity date, names (e.g. the operator of the sterilizer), or contents of the packaging.* ". Name of the operator corresponds to the operator's identifier). In view of Amhof, it would have been obvious to one of an ordinary skilled in the art at the time of the applicant's invention to have modified Friedman/Sanaka as already applied to claim 1 above to include the feature that the clients monitoring the functioning of sterilizers/washers assigns an operator identifier for identifying an operator of the antimicrobial device identified by the device identifier because it will enable the clients to track and correlate as to who has carried out the sterilization cycle, and to generate and store such records for future references.

Friedman discloses a communication server interface in bi-directional communication with the at least one instrument tracking client and the at least one antimicrobial treatment device, said communication server interface programmed to: receive data from an instrument tracking client and transmit data from the communication server interface to an antimicrobial treatment device (see at least Fig.1 and paragraphs 0009- 0013, 0042-0043 wherein " Hospital information system server " 30" is capable of communicating with both instrument tracking clients and the treatment device, to transmit and receive requests and data. Therefore this application when applied to Friedman/Sanaka/Amhof Is capable of receiving data from client computers and transmitting that data to an antimicrobial device and that data can include any type of data depending upon requirement that is for sterilization cycles to be implemented in Sanaka for sterilizing lenses can include

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sterilization device identifier, load identifier and the operator identifier in the form of operator's name (see Sanaka, see Fig.9,31 and col.12, lines 30-55).

Regarding claim 2, Friedman/Sanaka/Amhof discloses that the information management system according to claim 1, wherein said communication server interface includes a communication server installed on a general purpose computer system (see Friedman, at least paragraph 0052-0053).

Regarding claim 4, Friedman/Sanaka/Amhof discloses an information management system according to claim 1, wherein said system further comprises a computer network for connecting said respective general purpose computer system with said communication server interface (see Friedman, at least Fig.1 and paragraph 0041).

Regarding claim 5, Friedman/Sanaka/Amhof discloses that the information management system according to claim 1, wherein said antimicrobial treatment device is selected from the group consisting of a sterilizer and a washer (Already covered in claim 1 that the device is a sterilizer).

6.2. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman/Sanaka/Amhof as applied to claim 2 above, and further in view of Mukherjee (US Patent 6,314,415).

Regarding claim 3, Friedman/Sanaka/Amhof does not disclose that said communication server in claim 2 is implemented as at least one of a Component Object Model (COM), a COM+, and a Distributed Component Object Model (DCOM). However,

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Mukherjee discloses use of Component Object Model (COM), a COM+, and a Distributed Component Object Model (DCOM) (see at least col.5, lines 23-46 and col.6, lines 37-col.7, line 27). In view of Mukherjee, it would have been obvious to one of an ordinary skill in the art at the time of the applicant's invention to have modified Friedman/Sanaka/Amhof to incorporate Mukherjee's teaching of using Component Object Model (COM), a COM+, and a Distributed Component Object Model (DCOM) because it will facilitate insertion of components [COM] into various systems and configurations and avoiding redundant and unnecessary information and permit changes to the user interfaces without relying on "hard coded" software (see Mukherjee, col.2, lines 19-24).

6.3. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Friedman/Sanaka/Amhof as applied to claim 1 above, and further in view of Gillis et al. (US Publication 2005/0074833, herein after referred to Gilles).

Regarding claim 14, Friedman/Sanaka/Amhof as applied to claim 1 above does not teach the operator's function of entering the operator identifier at the start and end of the antimicrobial treatment cycle. However, in the same field of endeavor, Gilles suggests f entering operator's name while running the sterilization cycle (see at least fig.8 B. " By...." Paragraphs 0079, and 0088 which show that the operator's name/identification is required to be recorded on the label of the instrument/item being sterilized .). In view of Gilles, it would have been obvious to one of an ordinary skilled in the art at the time of the applicant's invention to have modified Friedman/Sanaka/Amhof as already applied to claim 1 above to include the operator's function of entering the operator identifier at the start and end of the antimicrobial treatment cycle because it will enable the clients to track and correlate as to who has carried out the sterilization cycle, and to generate and store such records for future references.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yogesh C. Garg whose telephone number is 571-272-6756. The examiner can normally be reached on M-F(8:30-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Smith can be reached on 571-272-6763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Yogesh C Garg  
Primary Examiner  
Art Unit 3625

YCG  
7/13/2006